

### ***REMARKS***

Claims 1 through 26 continue to be in the case.

Claims 1-2, 4-6, 8-9, 11, 14-15, 17-18, 20, 22-25 are being amended.

New claims 27 through 29 are being submitted.

New claim 27 is based on the language of claims 1, 2, 5, 7, Fig.1 and on the specification, page 13, lines 12 through 17.

New claim 28 is based on the language of claims 1, 3, 6, Fig.2 and on the specification, page 13, line 18 through page 14, line2.

New claim 29 is based on the language of claim 26.

Applicant submits the following additional remarks relative to the operation of the invention:

The invention device is used in GPE (gastronomy per endoscopic). In the case of gastronomy per endoscopic the surgeon uses a hole made previously. The hole is made under local anaesthesia and it is not necessary to have a hospital environment. The skin and the wall of the organ are connected together by a tube having a collar on each end. The skin and the wall of the organ weld together after approximately two months and then the surgeon can remove the tube. Thus there is present a hole in the skin of the patient and the surgeon can introduce the invention device through this hole. This

introduction of the device through the hole in the skin is possible, because the collar 8 is fixed on the distal (second) part (4) and is flexible.

One part of the pusher 16 shown in Fig. 2 is oval as can be recognized in Fig. 3, and this part is adapted to be inserted into the central portion 18 of the distal (second) part 4. The (first) part 2 has cylindrical shape and a portion of the pusher 16 disposed in front of the (first) part 2 is also of cylindrical shape. This way, the surgeon can immobilize the collar 6 of the (first) part 2 for example by hand and the surgeon can screw the (second) part 4 with the pusher 16.

According to Fig. 1, there is shown a cylindrical portion of the first part 2 and of the second part 4. The surgeon can immobilize the second part 4 by engaging the legs 12 into the slot 10. The surgeon can immobilize the collar 6 in this way and can screw the distal (second) part 4 with the tool 14. The surgeon can insert the pusher 16 with the tool 14 to introduce the invention device into the body.

According to Aubin, the incision is made under total anaesthesia and a medical act is required in a medical and hospital environment. A cylindrical sleeve 52 is glued to a cylindrical portion (Aubin reference, column 5, lines 30 to 35). In this manner a welding is furnished between the sleeve 52 and the portion 14. The portion 14 is thereby immobilized and no adjustment is possible. The surgeon is limited to introduce and to remove the device according to Aubin.

Applicant is submitting additional drawings for easier recognition of the present invention.

5. Claims 1, 2, 5 and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,344,435 to Aubin.

Aubin discloses a tube 14, skin collar 18, intravisceral collar 16 and means of immobilization (screw threading). See Figures 1-5.

Applicant respectfully disagrees.

The present application Claim 1 requires the intravisceral collar (8) to form a separate part from the transparietal tube. The reference Aubin teaches the rigid flange (collar) 16 and the central cylindrical portion 14 as the integral parts of the spool-shape member (tube) 12 (please compare also Figs.1 and 2 of the Aubin reference).

The present application Claim 1 requires the intravisceral collar (8) constructed so that its shape can be changed by the practitioner (please compare Fig.1 and 2 of the present application) to allow the intravisceral collar (8) to pass inside the organ directly from the outside of the patient's body. The reference Aubin teaches rigid flange (collar) 16 without any possibility to change the dimensions of the flange 16. As the flange 16 of the Aubin reference is clearly much more greater in diameter than the aperture in the patient's body and rigid (unchangeable), then the flange 16 of the Aubin

reference can be inserted only together with the whole spool-shape member (tube) 12 and only from the inside of the patient's body before the coupling 60 made.

The present application Claim 1 requires at least two parts (2 and 4) of the tube as separate parts from both collars. The Aubin reference shows only one single tube (central cylindrical portion 14) made as a single part with the flange (collar) 16.

In addition to, the Claim 1 of the present application requires these parts 2 and 4 moveable axially both during the device installation (from the outside of the patient's body) and during the tube length correction permanently, if necessary, during the whole period of treatment. The Aubin reference tube (central cylindrical portion) 14 has a fixed length that cannot be adjusted. Then the Aubin reference tube 14 is one-time installed (from the inside of the the patient's body, not outside, because of the too large rigid collar 16) and the tube 14 can not move axially after installation, in order not to loose the contact of the flange (collar) 16 with the internal surface of the patient's body.

The Claim 2 of the present application requires pusher 16 introduced inside the tube to change the shape of the intravisceral collar (8). The Aubin reference does not teach anything about any part formed like a pusher for an intravisceral collar 16 shape changing. Parts 32 and 76 are disposed inside the tube 14 of the Aubin reference, but these parts 32 and 76 are holding the cannula 24 tightly, and the collar 16 of the Aubin reference remains rigid all the time.

The Claim 5 of the present application requires the "telescopic" transaparietal tube (2, 4) comprising at least two end parts (2, 4). The Aubin reference clearly shows only one single tube (central cylindrical portion 14) without any telescopically fitted parts.

The Claim 6 of the present application requires the screwing 26 for the tube parts (2, 4) connection one to the other. The Aubin reference clearly shows single tube 14 without tube parts; then, screwing would be useless for the single tube of the Aubin reference.

Concluding, the claims under consideration clearly define the present invention over the Aubin reference.

*The Office Action refers to Claim Rejections - 35 USC § 103.*

6. Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Aubin.

Aubin discloses the claimed invention as shown above. Aubin, however, does not disclose expressly a bayonet fitting.

Applicant respectfully disagrees.

The Claim 7 of the present application requires the tube parts (2, 4) sliding axially one relative to the other to secure the relative mobility between the parts 2 and 4. The Aubin reference shows only a single tube 14 without any tube parts; then further, without relative sliding and mobility between the tube parts. The absence in the Aubin reference of the several tube parts movable relatively in axial direction is the critical issue in the patentability of the present application, although the Aubin reference also does not meet many other requirements of the present application, as said above.

The Office Action continues that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to

substitute a bayonet fitting for a screw fitting because Applicant has not disclosed that a bayonet fitting provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the screw fitting of Aubin because a screw fitting and bayonet fitting are both well known and used interchangeably in the art for mechanical connectors. Therefore, it would have been an obvious matter of design choice to modify Aubin to obtain the invention as specified in claim 7.

Applicant respectfully disagrees.

Applicant submits that by having a different construction with a bayonet fitting is sufficient to define the present invention over the Aubin reference. According to Applicant's specification, page 13, lines 14 to 18: "Immobilisation of the distal part 4 of the tube is obtained by means of a "bayonet" device 10, 12, with slots 10 being provided on the distal part 4 of the tube to allow the latter to be held by a specific tool 14 provided with lugs 12." The bayonet furnishes the advantage of immobilizing the distal (second) part 4. The bayonet is used for the particular purpose of immobilizing the distal (second) part 4. The stated purpose is having an adjustable length between the collars 6 and 8 and the bayonet enables such construction.

7. Claims 3 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Aubin in view of U. S. Patent No. 5,391,156 to Hildwein et al. (hereinafter "Hildwein"). Aubin shows the claimed invention as shown above except for a noncircular opening and a pusher. Hildwein discloses a portal having a noncircular opening 142 and pusher 174. See Figure 28. It would have been obvious to one of ordinary skill in the art to modify the invention of Aubin with a noncircular opening and corresponding pusher, as suggested by Hildwein, to maintain a specific orientation between the pusher and the opening.

Applicant respectfully disagrees.

The Claim 3 of the present application requires screwing (26) to secure the relative mobility between the two parts (2 and 4) of the transparietal tube. The Aubin reference shows only a single tube 14 without any tube parts; then, a relative mobility between the in Aubin not available parts is absent in the Aubin reference and a screwing would be useless for the single tube.

The Claim 3 of the present application requires a specific tool 16 introduced inside the non-circular axial opening (18) of the distal part 4 and comprising at least one area of complementary cross-section, in order for the distal part 4 to be rendered immobile in the rotational direction. The Aubin



reference does not teach anything about a part like pusher for the intravisceral collar 16 shape changing. Parts 32 and 76 are disposed inside the tube 14 of the Aubin reference, but these parts 32 and 76 are only holding the cannula 24 tightly, and the collar 16 of the Aubin reference remains rigid all the time. Then, the Aubin reference does not have any parts of the tube, and the Aubin reference does not provide any non-circular axial opening inside the tube 14 and nor the specific tool for engaging this opening, as these opening and tool would be useless for the static device of the Aubin reference.

The Claim 4 of the present application requires the pusher with non-circular cross-section to traverse the axial opening of complementary shape in the distal part (4) in order to render the distal part 4 immobile rotationally. The Aubin reference shows only single tube 14 without separate distal part of the tube. Then the Aubin reference does not provide any rotational movement of the tube or the parts of the tube, as the Aubin reference is one-time installed with fixed length of the tube and without any further changes in the tube length.



When combining the pusher (or any tool) with non-round cross-section described in the Hildwein reference with the device of the Aubin reference, it would be useless, because the Aubin reference device does not require any rotational movement of the tube. The more, the Aubin reference device seems not to prevent small rotational movement of the tube.

Thus, a combination of the Aubin reference and the Hildwein reference clearly fails to meet the requirements of the claims of the present application.

Entry of the amendment is respectfully requested.

Reconsideration of all outstanding rejections is respectfully requested.  
All claims as presently submitted are deemed to be in form for allowance and an early notice of allowance is earnestly solicited.

Respectfully submitted,

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